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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LAMBERTSON, DAVID A	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 02/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/705,940	FIKE, RICHARD M.	
	Examiner	Art Unit	
	David A. Lambertson	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,15,16,22-29,31-34 and 36-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,15,16,22-29,31-34 and 36-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed November 23, 2004. Amendments were made to the claims.

Claims 1-10, 15, 16, 22-29, 31-34 and 36-44 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed July 26, 2004, that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

Information Disclosure Statement

The information disclosure statement filed September 22, 2004 has been considered, and a signed and initialed copy of the form PTO-1449 has been attached to this Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 6, 8, 10, 15, 16, 28, 29, 31-33, 36, 40 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Fluka (as cited in the previous Office Action). **This rejection is maintained for the reasons set forth in the previous Office Action.**

Response to Arguments Concerning Claim Rejections - 35 USC § 102

Applicant's arguments filed November 23, 3004 have been fully considered but they are not persuasive. The following grounds of traversal are provided concerning the rejections under 35 USC § 102:

1. It is argued that the Fluka reference does not qualify as 102(b) art due to the lack of a publication date (see for example page 12, fourth paragraph of Applicant's arguments).

2. It is argued that Fluka fails to teach "a method for producing a *eukaryotic* culture medium" (original emphasis)(see for example page 12, fifth paragraph).

Applicant's arguments are not found convincing for the following reasons:

1. Careful inspection of the Fluka reference clearly indicates that the original publication of the "Terrific Broth" media formulation was published in 1987 (see the footnotes at the bottom of the page). Thus, there is a clear publication date for "Terrific Broth" which is more than one-year prior to the filing date of the instant application.

2. It is important to note that the instant claims are drawn to a method of *making* a medium composition, and not to a method of *using* the composition. The instant claims were amended to contain the language "eukaryotic culture medium;" however, there is no functional language or ingredient associated with the term "eukaryotic culture medium" in either the claims or the instant specification, making it impossible to discern between which media is eukaryotic and which is prokaryotic. In other words, the term "eukaryotic culture medium" refers to an intended use of the culture medium, and therefore does not carry any patentable weight.

Furthermore, simply because the media preparations of Fluka is not *typically* used for the propagation of eukaryotic cells does not mean that it *cannot* be used for the propagation of eukaryotic cells. Indeed, Terrific Broth medium carries all of the necessary components to support the growth of yeast cells (a nitrogen and carbon source, in the form of the protein hydrolyzate, yeast extract and glycerol), which are eukaryotic cells. Thus, absent any evidence that Terrific Broth cannot support the growth of eukaryotic cells such as yeast (which is not provided in the arguments), the methods of making the medium composition taught by Fluka still anticipate the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 5, 6, 8, 10, 15, 16, 28, 29, 31-33, 36, 40, 41 and 3*, 4*, 7*, 9*, 22-27*, 34*, 37-39* and 42-44* are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/36051 (as cited in the previous Office Action) in view of Fluka (as cited in the previous Office Action, and as applied to claims 1, 2, 5, 6, 8, 10, 15, 16, 28, 29, 31-33, 36, 40 and 41 above) (Note-* represents the claims rejected by the combined references). **This rejection is maintained for the reasons set forth in the previous Office Action.**

Response to Arguments Concerning Claim Rejections - 35 USC § 103

Applicant's arguments filed November 23, 3004 have been fully considered but they are not persuasive. The following grounds of traversal are provided concerning the rejections under 35 USC § 103:

1. It is again argued that Fluka is not a proper reference under 35 USC § 102(b) due to the lack of a qualifying date of publication.

2. It is argued that the motivation to combine provided by the Office (that each reference "allegedly concerns the preparation of a medium that has a desired pH upon reconstitution") is not "clear and particular evidence of a motivation to combine or modify the cited references" (see for example pages 16-17, bridging paragraph of Applicant's arguments).

3. It is argued that the Office's statement that WO 98/36051 suggests omitting "extraneous pH-adjusting agents form the media preparations is incorrect and does not suggest modifying or combining the references" (see for example page 17 of Applicant's response). Furthermore, it is argued that WO 98/36051 does not suggest using anything other than an acid or a base to adjust the pH of the media formulation.

Applicant's arguments have been considered but are not found convincing because of the following reasons:

1. It is reiterated from above that the Fluka reference clearly indicates that the media preparation of Terrific Broth was available in the prior art as of 1987.

2. It is first important to recognize that the statement that the two references concern "the preparation of a medium that has a desired pH upon reconstitution" is not the motivation statement provided by the Office, as suggested by Applicant. Rather, this statement merely

provides the reason why it would be *obvious* to combine the teachings. Thus, Applicant's argument that this statement does not provide a clear and particular motivation to combine the cited references is moot.

In contrast, the Office sets forth that the motivation to combine the references comes from the desire to formulate a media composition with a desired pH upon reconstitution of the formulation without the addition of exogenous sources (meaning pH-adjustment after the formulation has been reconstituted). Fike (WO 98/36051) teaches the use of an acid or a base to formulate a automatically pH-adjusting media formulation (which provides significant cost and time saving effects, as well as limits the chance of contamination; see for example page 38, lines 4-10 of Fike), while Fluka teaches the adjustment can be made using pH-opposing forms of buffer salts instead of an acid or a base. In other words, the combination of references shows that an automatically pH-adjusting medium can be made either by using pH-opposing forms of buffer salts (Fluka) or an acid/base (Fike). The *desirability* of obtaining a automatically pH-adjusting buffer taught by Fike is what provides the clear and particular motivation to combine the references as obvious variants.

3. The Office disagrees that Fike does not teach the omission of "extraneous pH-adjusting agents" (i.e., the addition of pH-adjusting agents following the reconstitution of the powdered medium). Fike clearly indicates the addition of pH-adjusting agents to a powder *prior to reconstitution* (see for example page 20, lines 14-21); thus, there is no need to adjust the pH after reconstitution, and therefore no need for "extraneous pH-adjusting agents."

The fact that Fike does not suggest using anything besides an acid or a base to adjust the pH of the media compositions discounts Fike as an *anticipatory* reference, but not as an

obviousness-type reference, which is the nature of the instant rejection. Fike teaches using an automatically pH-adjusting media formulation wherein an acid or a base is used to establish the pH; Fluka clearly teaches the use of opposing buffer salts for a automatically pH-adjusting medium. It is the combination of these references, and not Fike alone, that makes the claimed invention obvious. The Office clearly indicated why it was obvious to combine the references (both references teach the formulation of automatically pH-adjusting culture medium, and it is clear that the use of pH-opposing buffer salts can give the same results as using an acid or base directly), and why the skilled artisan would be motivated to combine the references (the desirability of an automatically pH-adjusting medium for time and cost savings, as well as decreased chance of contamination). Thus, the fact that Fike alone does not teach the use of pH-opposing buffer salts to establish an automatically pH-adjusting medium is insufficient in itself to traverse the instant rejection.

Allowable Subject Matter

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Lambertson, Ph.D.
AU 1636

JAMES KETTER
PRIMARY EXAMINER